

CLAIMS:

1. A method for inducing an analgesic response to neuropathic or inflammatory pain in a mammal, said method comprising administering to the mammal, flupirtine or a pharmaceutically acceptable salt, derivative, homolog or analog in an amount effective to reduce the level of or to otherwise ameliorate the sensation of pain.
2. The method of Claim 1 wherein flupirtine or a pharmaceutically acceptable salt is administered.
3. The method of Claim 1 or 2 further comprising the administration of an analgesic compound concurrently, separately or sequentially to the flupirtine.
4. The method of Claim 3 wherein the analgesic compound is an opioid.
5. The method of Claim 4 wherein the opioid is selected from the list consisting of fentanyl, oxycodone, codeine, dihydrocodeine, dihydrocodeinone enol acetate, morphine, desomorphine, apomorphine, diamorphine, pethidine, methadone, dextropropoxyphene, pentazocine, dextromoramide, oxymorphone, hydromorphone, dihydromorphine, noscapine, papaverine, papaveretum, alfentanil, buprenorphine and tramadol and pharmaceutically acceptable derivates, homologs or analogs thereof.
6. The method of Claim 5 wherein the opioid is morphine or a pharmaceutically acceptable salt thereof.
7. The method of Claim 4 or 5 or 6 further comprising the administration of another active agent concurrently, separately or sequentially to flupirtine and the opioid.
8. The method of Claim 7 wherein the active agent is an anti-cancer agent, an analgesic agent, a p-glycoprotein inhibitor, a drug which acts on the central nervous system, a muscle relaxant, an anti-Parkinson's Disease agent, an anti-Alzheimer's Disease

agent, an anti-inflammatory agent, an anti-microbial agent, a hormone, a diuretic, an ophthalmic agent, or a cardiovascular drug or a combination thereof.

9. The method of claim 8 wherein the other active agent is selected from the list consisting of aspirin, indomethacin, naproxen, fenoprofen, sulindac, diclofenac, indoprofen, nitroglycerin, propanolol, valproate, timolol, atenolol, alprenolol, cimetidinze, clonidine, imipramine, levodopa, chloropromazine, reserpine, methyl-dopa, dihydroxyphenylalanine, provaloxyloxyethyl ester of alpha -methyldopa hydrochloride, theophylline, calcium gluconate, ferrous lactate, vincamine, diazepam, phenoxybenzamine, blocking agents and pharmaceutically acceptable salts, derivatives, homologs or analogs thereof.

10. The method of any one of Claims 4 to 9 wherein the opioid does not induce overt sedation in the presence of flupirtine.

11. The method of Claim 1 wherein flupirtine is administered in an amount of about 0.5 mg/kg to about 20 mg/kg of body weight.

12. The method of Claim 1 wherein the mammal is human.

13. A delivery system for inducing an analgesic response in a mammal having neuropathic or inflammatory pain said delivery system comprising combined or separate formulations of flupirtine or a pharmaceutically acceptable salt, derivative, homolog or analog thereof; an opioid; and optionally one or more further active agents.

14. The delivery system of Claim 13 wherein flupirtine or a pharmaceutically acceptable salt is administered.

15. The delivery system of Claim 13 or 14 further comprising the administration of an analgesic compound concurrently, separately or sequentially to the flupirtine.

16. The delivery system of Claim 15 wherein the analgesic compound is an opioid.

17. The delivery system of Claim 16 wherein the opioid is selected from the list consisting of fentanyl, oxycodone, codeine, dihydrocodeine, dihydrocodeinone enol acetate, morphine, desomorphine, apomorphine, diamorphine, pethidine, methadone, dextropropoxyphene, pentazocine, dextromoramide, oxymorphone, hydromorphone, dihydromorphone, noscapine, papaverine, papaveretum, alfentanil, buprenorphine and tramadol and pharmaceutically acceptable derivates, homologs or analogs thereof.

18. The delivery system of Claim 17 wherein the opioid is morphine or a pharmaceutically acceptable salt thereof.

19. The delivery system of Claim 16, or 17 or 18 further comprising the administration of another active agent concurrently, separately or sequentially to flupirtine and the opioid.

20. The delivery system of Claim 19 wherein the active agent is an anti-cancer agent, an analgesic agent, a p-glycoprotein inhibitor, a drug which acts on the central nervous system, a muscle relaxant, an anti-Parkinson's Disease agent, an anti-Alzheimer's Disease agent, an anti-inflammatory agent, an anti-microbial agent, a hormone, a diuretic, an ophthalmic agent, or a cardiovascular drug or a combination thereof.

21. The delivery system of Claim 20 wherein the other active agent is selected from the list consisting of aspirin, indomethacin, naproxen, fenoprofen, sulindac, diclofenac, indoprofen, nitroglycerin, propanolol, valproate, timolol, atenolol, alprenolol, cimetidinze, clonidine, imipramine, levodopa, chloropromazine, reserpine, methyl-dopa, dihydroxyphenylalanine, provaloxyloxyethyl ester of alpha -methyldopa hydrochloride, theophylline, calcium gluconate, ferrous lactate, vincamine, diazepam, phenoxybenzamine,

blocking agents and pharmaceutically acceptable salts, derivatives, homologs or analogs thereof.

22. The delivery system of Claim 13 wherein the opioid does not induce overt sedation in the presence of flupirtine.

23. A method of treating a disease or physiological condition in a mammal wherein a symptom of said disease or condition is neuropathic or inflammatory pain, said method comprising administering to said mammal an effective amount of an agent to treat the disease or physiological condition an amount of flupirtine or a pharmaceutically acceptable salt, derivative, homolog or analog thereof.

24. A method of treating a disease or physiological condition of Claim 23 wherein flupirtine or a pharmaceutically acceptable salt is administered.

25. A method of treating a disease or physiological condition of Claim 23 or 24 further comprising the administration of an analgesic compound concurrently, separately or sequentially to the flupirtine.

26. A method of treating a disease or physiological condition of Claim 25 wherein the analgesic compound is an opioid.

27. A method of treating a disease or physiological condition of Claim 26 wherein the opioid is selected from the list consisting of fentanyl, oxycodone, codeine, dihydrocodeine, dihydrocodeinone enol acetate, morphine, desomorphine, apomorphine, diamorphine, pethidine, methadone, dextropropoxyphene, pentazocine, dextromoramide, oxymorphone, hydromorphone, dihydromorphine, noscapine, papaverine, papaveretum, alfentanil, buprenorphine and tramadol and pharmaceutically acceptable derivates, homologs or analogs thereof.

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28. A method of treating a disease or physiological condition of Claim 27 wherein the opioid is morphine or a pharmaceutically acceptable salt thereof.

29. A method of treating a disease or physiological condition of Claim 26 or 27 or 28 further comprising the administration of another active agent concurrently, separately or sequentially to flupirtine and the opioid.

30. A method of treating a disease or physiological condition of Claim 29 wherein the active agent is an anti-cancer agent, an analgesic agent, a p-glycoprotein inhibitor, a drug which acts on the central nervous system, a muscle relaxant, an anti-Parkinson's Disease agent, an anti-Alzheimer's Disease agent, an anti-inflammatory agent, an anti-microbial agent, a hormone, a diuretic, an ophthalmic agent, or a cardiovascular drug or a combination thereof.

31. A method of treating a disease or physiological condition of Claim 30 wherein the other active agent is selected from the list consisting of aspirin, indomethacin, naproxen, fenoprofen, sulindac, diclofenac, indoprofen, nitroglycerin, propanolol, valproate, timolol, atenolol, alprenolol, cimetidinze, clonidine, imipramine, levodopa, chloropromazine, reserpine, methyl-dopa, dihydroxyphenylalanine, provaloxyloxyethyl ester of alpha -methyldopa hydrochloride, theophylline, calcium gluconate, ferrous lactate, vincamine, diazepam, phenoxybenzamine, blocking agents and pharmaceutically acceptable salts, derivatives, homologs or analogs thereof.

32. A method of treating a disease or physiological condition of any one of Claims 26 to 31 wherein the opioid does not induce overt sedation in the presence of flupirtine.

33. A method of treating a disease or physiological condition of Claim 23 wherein flupirtine is administered in an amount of about 0.5 mg/kg to about 20 mg/kg of body weight.

34. A method of treating a disease or physiological condition of Claim 23 wherein the mammal is human.

35. The method of Claim 23 wherein the disease or condition is cancer, arthritis, backpain, a broken bone or strained muscle.

36. A slow release or sustained release formulation of flupirtine or a pharmaceutically acceptable salt, derivative, homolog or analog thereof comprising:

(a) a deposit-core comprising an effective amount of the active substance and having defined geometric form, and

(b) a support-platform applied to said deposit-core, wherein said deposit-core contains at least the active substance, and at least one member selected from the group consisting of:

(i) a polymeric material which swells on contact with water or aqueous liquids and a gellable polymeric material wherein the ratio of the said swellable polymeric material to said gellable polymeric material is in the range 1:9 to 9:1, and

(ii) a single polymeric material having both swelling and gelling properties, and wherein the support-platform is an elastic support, applied to said deposit-core so that it partially covers the surface of the deposit-core and follows changes due to hydration of the deposit-core and is slowly soluble and/or slowly gellable in aqueous fluids.

37. The slow release or sustained release formulation of Claim 36 further comprising an opioid and optionally one or more other active agents.

38. The slow release or sustained release formulation of Claim 35 or 36 wherein the support platform comprises a hydroxypropylmethyl cellulose.

39. The slow release or sustained release formulation of Claim 35 or 36 or 37 or 38 wherein the support platform comprises a plasticizer, a binder, a hydrophilic agent and a hydrophobic agent.

40. An agent for inducing an analgesic response in a mammal, the agent comprising flupirtine or a pharmaceutically acceptable salt, derivative, homolog or analog thereof and optionally an analgesic compound such as an opioid and optionally an active compound for treating a condition, disease or pathology. In one particular example, the present invention contemplates a treatment protocol for cancer, the protocol comprising the administration of a anti-cancer agent and/or radiation therapy in combination with flupirtine and optionally an opioid or a pharmaceutically acceptable salt, derivative, homolog or analog thereof.

41. Use of flupirtine or a pharmaceutically acceptable salt, derivative, homolog or analog thereof in the manufacture of a medicament for use in combination with an opioid for the treatment of neuropathic or inflammatory pain.

42. Use of flupirtine or a pharmaceutically acceptable salt, derivative, homolog or analog thereof and optionally an opioid and further optionally an active agent such as an anti-cancer agent in the manufacture of one or more medicaments for the treatment of neuropathic or inflammatory pain.